

REMARKS

I. STATUS OF THE APPLICATION

Claims 1 – 26 were filed in the original application. In response to the Examiner's Restriction Requirement in the Office Action mailed April 10, 2006, the Applicants cancelled claims 1 – 26, 30, and 39 – 49, and added claims 50 – 87. In the present Response to the Office Action of July 27, 2006 the Applicants have cancelled claims 36, 61, 72 and 79, and amended claims 27, 28, 37, 53, 62, 69, 73, 75, and 80.

In the Office Action of July 27, 2006 the Examiner has made 3 rejections. The currently pending rejections are:

1. Claims 27, 28, 32-34, 36-38, 50, 69, 70, 72-76, 79, 80, 81, 84 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Hurst *et al.* (Rapid Comm. Mass Spectrom. (1996) 10:377-382.), hereinafter "Hurst".
2. Claims 27-29, 31-35, 38, 50-60, 63-71, 74-78 and 81-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman *et al.* (Arch. Virol. (2001) 146:2275-2289.), hereinafter "Hoffman".
3. Claims 36, 37, 61, 62, 72, 73, 69 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman in view of Koster (WO 98/20166), hereinafter "Koster".

II. STATUS OF THE AMENDMENTS

In the present Amendment and Response to the Office Action of May 26, 2006 the Applicants herein amend claims 27, 28, 37, 53, 62, 69, 73, 75 and 80, and cancel claims 36, 61, 72 and 79. The Applicants note that the amendments and cancellation of claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections. The amendments of claims presented herein are made solely for the purpose of expediting the patent application process in a manner consistent with the

U.S. Patent and Trademark Office's Patent and Business Goals (PBG),¹ and without waiving the right to prosecute the amended claims (or similar claims) in the future.

Therefore, claims 27 - 29, 31 - 35, 37, 38, 50 - 60, 62 - 71, 73 - 78, and 80 - 87 are currently pending in the application.

The Office Action of July 27, 2006 states that "the phrase 'base composition' appears repeatedly in the claims and specification but no definition of this term was found." (Office Action of July 27, 2006, page 2). In order to further the prosecution of the present case, while not acquiescing to the Examiner's argument, and retaining the right to prosecute the original claims (or similar claims) in the future, the Applicants herein amend claims 27, 53, 69 and 75 to read "said base compositions are calculated from molecular mass measurements of the amplification products using a mass spectrometer, wherein said base compositions identify the number of each individual nucleotide present in said amplification products without sequencing said amplification product". The Applicants respectfully note that in claims 27, 53, 69 and 75, and claims dependent thereupon, the step of measuring base composition includes identification of the number of each nucleotide in the amplification product, independent of the linear arrangement of said nucleotides. Such a measurement is found throughout the Specification.

The Applicants note that the amendments and cancellations of claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections. The amendments and cancellations of claims presented herein are made solely for the purpose of expediting the patent application process in a manner consistent with the U.S. Patent and Trademark Office's Patent and Business Goals (PBG),² and without waiving the right to prosecute the amended claims (or similar claims) in the future.

III. STATUS OF THE REJECTIONS

A. The Claims are not Anticipated by Hurst

¹ 65 Fed. Reg. 54603 (Sept. 8, 2000).

² Ibid.

In the Office Action of July 27, 2006 the Examiner has rejected claims 27, 28, 32-34, 36-38, 50, 69, 70, 72-76, 79, 80, 81, 84 and 85 as allegedly being anticipated by Hurst. In the present Amendment and Response to Office Action of July 27, 2006 the Applicants have cancelled claims 36, 72 and 79 thereby rendering these rejections moot.

The Federal Circuit has stated the relevant analysis for anticipation as follows:

"A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference."³

The Applicants respectfully submit that Hurst does not teach each and every element as set forth in the claims.

For example, the Examiner notes "see page 379, figure 1, where Hurst performs MALDI-TOF on both PCR products to determine base composition of the mass of the PCR product, and shows that this is a feasible method of detecting *Legionella*." (Office Action of July 27, 2006, page 3). Also, the Examiner notes "With regard to claim 36, Hurst teaches the base compositions of both the mip and 5S rRNA pcr products (see page 379, figure 1)." (Office Action of July 27, 2006).

As noted above, the Applicants have amended claims 27, 53, 69 and 75 to read "said base compositions are calculated from molecular mass measurements of the amplification products using a mass spectrometer, wherein said base compositions identify the number of each individual nucleotide present in said amplification products without sequencing said amplification product". The Applicants submit that Hurst fails to teach these elements of the claims.

As well, the Hurst reference does not teach or suggest primers designed to hybridize to any pathogens other than to *Legionella*.

In view of the above, the Applicants respectfully request that this rejection be withdrawn.

B. The Claims are not Anticipated by Hoffman

³ *Verdegaal Bros. V. Union Oil of California*, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987).

In the Office Action of July 27, 2006 the Examiner has rejected claims 27-29, 31-35, 38, 50-60, 63-71, 74-78 and 81-87 as allegedly being anticipated by Hoffman.

The Applicants respectfully submit that Hoffman does not teach each and every element as set forth in the claims. For example, the Examiner notes that Hoffman teaches “(b) determining the base compositions of at least two members of said plurality of amplification products wherein said base compositions identify said pathogen in said sample (see page 2281, figure 3, where the base composition in terms of mass is determined by gel electrophoresis).” (Office Action of July 27, 2006, page 4).

As noted above, the Applicants have amended claims 27, 53, 69 and 75 to read “said base compositions are calculated from molecular mass measurements of the amplification products using a mass spectrometer, wherein said base compositions identify the number of each individual nucleotide present in said amplification products without sequencing said amplification product”. The Applicants submit that Hoffman fails to teach these elements of the claims.

In view of the above, the Applicants respectfully request that this rejection be withdrawn.

C. The Claims are not Rendered Obvious by Hoffman in View of Koster

In the Office Action of July 27, 2006 the Examiner has rejected claims 36, 37, 61, 62, 72, 73, 69 and 80 as allegedly being unpatentable over the combination of Hoffman in view of Koster. In the present Amendment and Response to Office Action of July 27, 2006 the Applicants have cancelled claims 36, 61, 72 and 79 thereby rendering these rejections moot.

A *prima facie* case of obviousness requires the Examiner to cite to a reference which a) discloses all the elements of the claimed invention, b) suggests or motivates one of ordinary skill in the art to combine the claim elements to yield the claimed invention, and c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements negates a finding of a *prima facie* case and, without more, entitles the Applicants to allowance of the claims in issue. (MPEP)

The Applicants assert that neither of the Examiner's references, alone or in combination, disclose all elements of the claimed invention. For example, neither Hoffman or Koster alone, or in combination, teach or suggest the element "wherein said base compositions identify the number of each individual nucleotide present in said amplification products without sequencing said amplification product".

Moreover, the Applicants respectfully submit that there is no motivation to combine the cited references in the manner suggested by the Examiner and, even if combined, there would be no expectation of success

In view of the amendments to the claims and the accompanying Declaration, the Applicants respectfully submit that the claims are in condition for allowance.

V. DOUBLE PATENTING

Claims 27-29, 31-38 and 50-87 are provisionally rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over particular claims of numerous co-pending applications. Upon indication of otherwise allowable subject matter, the Applicants will consider the filing of a Terminal Disclaimer.

CONCLUSION

All grounds of rejection of the Office Action of July 27, 2006 have been addressed, and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicant's claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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